Support for the Claims

Support for the amendments to the claims is found throughout the specification. More particularly, support for the amendments to claims 42 and 69 is found, *inter alia*, in claim 43. Support for the amendment to claim 64 is found, *inter alia*, on page 29, lines 8-13. In view of the foregoing support, Applicants respectfully request that the Examiner withdraw the rejection.

Rejection Under 35 U.S.C. § 102(e)

Claims 42-75 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 5,820,873 ("Choi, *et al.*"). The Examiner states that Choi, *et al.* teach liposomes for the delivery of bioactive agents comprising DODAC, DOPE, and PEG-ceramide and DODAC, DOPE, and PEG-DSPE. To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

"To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter" (see, *PPG Industries Inc. v. Guardian Industries Corp.*, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996)).

Choi, *et al.* teach a new class of polyethylene glycol modified ceramide lipids which can be used to form liposomes containing various biological agents or drugs. However, Applicants have amended claim 42 to recite a particle for introducing a nucleic acid into a cell, said particle comprising a cationic lipid, a conjugated lipid that inhibits aggregation of particles, and a nucleic acid, wherein said nucleic acid in said particle is ***resistant in aqueous solution to degradation with a nuclease***. As stated on page 4, lines 29-31, the particles described in the present invention are constructed in a way such that upon removal of a solubilizing component (*i.e.*, detergent or an organic solvent), the nucleic acid becomes protected from degradation. The particles thus formed are suitable for use in intravenous nucleic acid transfer as they are stable in circulation, of a size required for pharmacodynamic behavior resulting in access to extravascular sites and target cell populations. As the prior art reference does not disclose each and every aspect

of the claimed invention, the present invention is not anticipated. In view of the amendments to the claims, Applicants respectfully request that the Examiner withdraw the anticipation rejection.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 64 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as their invention.

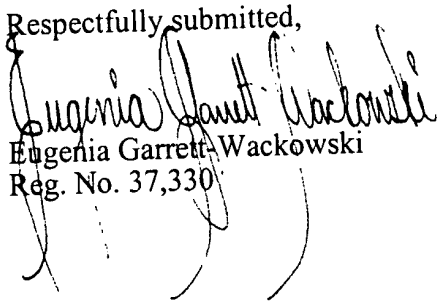
In order to expedite prosecution of the above-referenced patent application, claim 64 has been amended to set forth the amount of cationic lipid in the nucleic acid-lipid particle as any amount greater than 0% to about 20% of the lipid. Therefore, the particle of the invention meets the limitation set for in claim 42, from which claim 64 depends, which states that the particle of the invention "...comprises a cationic lipid..." In view of the amendments to the claims, Applicants respectfully request that the Examiner withdraw the rejection under U.S.C. § 112, second paragraph.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



Eugenia Garrett-Wackowski
Reg. No. 37,330

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
EGW/lls

WC 9037332 v1

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims

Claim 43 has been cancelled.

Claims 42, 64, and 69 have been amended as follows:

42. (Amended) A nucleic acid-lipid particle for introducing a nucleic acid into a cell, said particle comprising a cationic lipid, a conjugated lipid that inhibits aggregation of particles, and a nucleic acid, wherein said nucleic acid in said particle is resistant in aqueous solution to degradation with a nuclease.

64. (Amended) The nucleic acid-lipid particle of claim 42, wherein said cationic lipid comprises from an amount greater than 0% to about 20% of the lipid present in said particle.

69. (Amended) A pharmaceutical composition comprising a nucleic acid-lipid particle and a pharmaceutically acceptable carrier, said nucleic acid-lipid particle comprising a cationic lipid, a conjugated lipid that inhibits aggregation of particles, and a nucleic acid, wherein said nucleic acid in said particle is resistant in aqueous solution to degradation with a nuclease.